Amendments to the Drawings

Please replace Figure 1 with the accompanying Replacement Sheet for Figure 1.

Fig. 1 is amended by showing and labeling “device (10)”, as required by the Office.

REMARKS

In response to the Office Action of June 1, 2007, claims 1-5, 9, 12, 19, 21-23 and 26 are pending. Claim 26 is a new claim. Claims 1-4, 9, 12, 22 and 23 are currently amended. Claims 5 and 19 are previously presented and claim 21 is an original claim. Claims 6-8, 10, 11, 13-18, 20, 24 and 25 are canceled. None of the amendments constitute the addition of new matter.

Specification Amendments

The paragraph that spans pages 4-5 (e.g., starting on page 4, 10th paragraph) is amended to correct an obvious typographical error as required by the Office. Specifically, "he" is replaced with "the". In addition, that paragraph is further amended to correct a typographical error by replacing "collaps g" with "collapsing"

Claim Amendments

Claim 1 is amended to clarify the scope of the claimed invention. In particular, the reservoir is recited as "being formed by a membrane, wherein said membrane is comprised of flexible thermo-conductive material." Support for this amendment is found in the claims, such as claims 3, and 12-14, for example. Claims 3 and 12 are accordingly amended for consistency with this amendment.

Further, the membrane is functionally defined as "substantially equalizes the temperature of the expired air in said reservoir with communicating ambient air, thereby providing a means to decrease the dew point of the said expired air in order to reduce the humidity thereof and a means to decrease the temperature of said expired air". Support for this amendment is found in claims 12-14. Claim 12 is accordingly amended by deleting this language and claims 13-14 are canceled.

In addition, the claimed invention is further clarified by reciting that the "reservoir is contained within a casing of selectively variable volume." Support for that amendment is found throughout the specification, such as Figs. 1 and 4 (see particularly the legend descriptions); the sentence spanning pages 4-5; page 7, lines 1-3, for example.

Support for the language "wherein said absorption chamber is positioned downstream of the reservoir" is found in Fig. 1 and at page 5, 4th line from bottom ("absorption chamber 32 through which air passes from the inside of the flexible reservoir 22 to the mixing chamber 36 . . . to the lungs of the user").

Support for the language "a demand valve in said inspiratory path to facilitate communication with the ambient air as required" is found, for example, in claim 15; page 6, lines 23-25; Figs. 1 and 3 (where demand valve 38 is shown in communication with ambient air and inspiratory path as required).

Claim 2 is amended by changing the dependency from canceled claim 25 to claim 1, which incorporates claim 25.

Claims 3 and 4 are amended for conformance with amended claim 1 (providing a reservoir contained within a casing). Claim 3 is further amended to clarify that the casing volume variation "in turn determines the volume of said flexible reservoir." Support for this amendment is found at page 5, lines 3-11, for example.

Claim 9 is amended to change the dependency from canceled claim 6 to claim 1 and for clarity and in view of the amendments to claim 1. Claim 9 is further clarified by reciting the demand valve is adjustable to provide variable amounts of ambient air to adjust oxygen levels in the inspired air. Support for this amendment is found, for example at page 6, lines 13-15 (noting metered

amounts of ambient air provided by orifices 42) and page 6, lines 28-29 (noting orifices 42 can be replaced with demand valve 38).

Claim 26 is a new claim that is dependent from claim 1 that further recites that "the membrane comprises means for preventing said moisture from communicating with said CO_2 absorption chamber." Support for this amendment is found in canceled claims 17, 18.

The remaining amendments are made to correct claim dependency, for clarity, and/or consistency with the amendments discussed above. None of the amendments constitute the addition of new matter.

RESPONSE TO DETAILED ACTION

Drawing Amendments (Item 1)

The Office Action objects to the drawings under 37 CFR 1.84(p)(5) for not showing device (10) that is mentioned in the description. Replacement Figure 1 explicitly shows this reference sign (10).

Specification (Item 2)

The disclosure is objected to (see Item 2) because of an informality related to a typographical error where "he" should be "the". Applicant accordingly amends the description herein to correct that informality.

Claim Rejections 35 U.S.C. 102 Rejection (Items 3-4)

Claims 1, 2, 6, 9, 10, 15-17, 19, 24, and 25 are rejected under 35 U.S.C. 102(b) as being allegedly anticipated by Michielsen (3,575,167).

The Office alleges "Michielsen discloses a breathing apparatus for providing a rebreathable air mixture expired by a user which air mixture has a lower oxygen

concentration than the ambient air." Applicant respectfully traverses this rejection.

To fully anticipate a claim under a section 102 rejection, the reference must disclose every element of the claimed invention. In particular, Michielsen does not disclose every element of claim 1, as discussed below.

Communication with ambient air

Claim 1 recites "a demand valve in said inspiratory path to facilitate communication with the ambient air" (emphasis added). Because Michielsen is concerned with isolating the breather from an external "harsh" environment, Michielsen certainly does not teach or suggest any such fluid communication with ambient air and, instead, takes care to ensure there is no such communication with the ambient air or the external environment. As Michielsen does not teach or suggest that element, Applicant respectfully requests reconsideration and withdrawal of the section 102(b) rejection. Because the remaining claims depend from claim 1, Applicant requests the 102(b) rejection directed to the other claims be similarly withdrawn.

Michielsen cannot be used for hypoxic training

Michielsen is fundamentally different than the present invention in that Michielsen is directed to an apparatus that ensures a normoxic or hyperoxic breathing apparatus (see, e.g., col. 5, line 2 "oxygen continually metered into the canister"; col. 5, line 23 "a user may not be able to adjust the oxygen-metering valve 56 to maintain a flow precisely similar to his rate of oxygen absorption). Those statements suggest Michielsen is concerned with an apparatus whereby the level of oxygen is maintained within a narrow range of normoxic. As oxygen is absorbed by the user's respiratory system, Michielsen attempts to ensure the absorbed oxygen is replenished. The presently claimed invention, in contrast, is for hypoxic breathing for training purposes.

Although Michielsen generally uses the principle of rebreathing, that application relates to ensuring oxygen levels are not hypoxic (e.g., see col. 5, lines 1-3: "In contrast to prior closed-circuit breathing devices, replacement oxygen is continuously metered into the canister . . ."). Without such an oxygen canister, Michielsen states at col. 5, lines 11-18:

> The breathing apparatus 11 has some usages which do not require a gas bottle 52. Since the user metabolizes only a small portion of the oxygen in each breath, it is possible to breathe for a few minutes with the bottle 52 absent and fitting 53 capped. This provides an adequate period for certain uses of the apparatus. Use for emergency escape from a caisson or underwater craft is one such instance.

Furthermore, the breathing apparatus in Michielsen takes pain to isolate the closed-loop breathing from the external environment (e.g., by capping the fitting when oxygen bottle 52 is absent) as that apparatus is for "protecting from contaminated atmospheres of various kinds, diving, resuscitation, decompression and medical uses." Breathing in of such harsh environments (e.g., smoke-filled or underwater) is to be avoided, as reflected by the fact that Michielsen does not teach or suggest any fluid communication with the external environment. The only external communication is with a gas bottle 52 that hooks into gas input hose 54. Pending claim 1, in contrast, recites a demand valve in fluid communication with ambient air. Accordingly, Applicant requests the 102(b) rejection be withdrawn.

Demand valve

The Office alleges Michielsen discloses the use of a demand valve in communication with the inspiratory path in rejecting claims 15 and 16. Applicant notes pending claim 1 recites "a demand valve in said inspiratory path to facilitate communication with the ambient air as required". Such a demand valve is completely different than the demand valve of Michielsen. In Michielsen the demand valve is designed to limit the flow of air from the second compartment 14 to the mouthpiece for inspiration unless there is decrease in pressure on the

outlet side of the valve. The demand valve in Michielsen is further aimed at allowing for two-way air flow through the apparatus, if required.

In contrast, whilst the demand valve in the present invention is situated in the same relative position (in the inspiratory path downstream of the absorber material), it communicates with the environment or ambient air. As discussed, there is no teaching or suggestion in Michielsen that the demand valve communicate with the environment or ambient air as Michielsen takes pain to ensure the breather is isolated from the environment. In contrast, the demand valve of the present invention allows for mixing of the inspirable air prior to inspiration when the available volume is insufficient.

Variable volume

In rejecting claims 2, 24 and 25, the Office alleges Michielsen discloses "the volume of the reservoir (42) may be varied by compression of the reservoir (42)." Applicant traverses this rejection.

In particular, claim 1 recites "wherein said reservoir is contained within a casing of selectively variable volume." This clarifies that the claimed invention is directed to controlling the internal volume of the casing itself and not simply of the flexible reservoir bag. This is an important feature, as the ability to vary the volume of the casing enables the user to precisely control the volume of the reservoir bag. This element is not taught or suggested by Michielsen. Instead, all Michielsen teaches regarding this aspect is that the user is able to physically compress the bag manually thereby varying the volume. This is not equivalent to the presently claimed invention where the *potential* volume of the reservoir is precisely controlled by control of the casing volume. There is no teaching or suggestion in Michielsen regarding "a casing of selectively variable volume."

The capacity to regulate the volume of the reservoir bag with the casing makes the construction of a personalised training schedule possible. In this way, the

structural advantage provided by a casing of variable volume enables the apparatus of the present invention to be used as a training device as progressively higher altitudes can be simulated. A flexible reservoir bag only provides an advantage over a solid receptacle if the expansion of that flexible bag may in some way be precisely controlled. If the variation in volume is simply due to the volume of air that inflates it, there is no functional benefit over a solid receptacle. The fundamental difference between the two is illustrated by the following example.

Firstly, consider the case where a volume of air, equivalent to the volume of a particular user's exhalation, is released into a solid receptacle. Provided the internal volume of that receptacle is large enough, the air exhaled by the user will be stored within the receptacle until it is withdrawn.

Now, consider the same series of events with a flexible reservoir bag. Provided the flexible bag is of a sufficiently large volume, it offers no functional benefit over the solid receptacle as it does no more than inflate to accommodate the volume of air exhaled.

Then, consider the case where a flexible reservoir bag resides within a casing of variable volume. If the internal volume of that casing is variable, a functional benefit is made available to the user. The user is able to select the volume the reservoir bag may expand to by altering the internal volume of the casing. If for example, the internal volume of the casing is set such that the flexible reservoir bag is only able to expand to a volume capable of accepting 80% of the same exhaled volume of air from the same user as above, 20% of that volume of air will be released/exhausted to the environment. When the stored volume is inhaled, assuming an equivalent inspiration is made, 20% of the volume inspired must be sourced from the environment. If the user chooses to maintain the current selected internal volume of the apparatus, in every inspiration-exhalation

cycle, 20% of the air passing through the apparatus will be ambient air/fresh air coming in from the environment.

The ability to control the volume of air that enters the apparatus from the environment provides a tremendous benefit to any user in that different altitudes can be easily simulated without the need for any external air supplementation mechanisms connected to monitoring devices. The larger the internal volume of the reservoir bag's casing, the higher the altitude simulated as less air will enter from the environment during inspiration. Consequently, the partial pressure of oxygen is supplemented to a reduced extent and will therefore remain at a lower level. The converse is also true where the internal volume of the casing is decreased.

The presence of a casing of variable volume therefore provides for an easy, simple, efficient and safe way to simulate varying altitudes accurately and enables creation of individually tailored training regimes that may progress as desired simply by increasing the internal volume of the casing.

Because Michielsen does not teach or suggest a reservoir contained within a casing of selectively variable volume, Applicant requests the rejection of claim 1, and the claims depending therefrom be reconsidered and withdrawn.

Dual CO_2 absorption chambers

Pending claim 1 also recites a membrane that comprises a:

> thermo-conductive material that substantially equalizes the temperature of the expired air in said reservoir with communicating ambient air, thereby providing a means to decrease the dew point of the said expired air in order to reduce the humidity thereof and a means to decrease the temperature of said expired air.

Michielsen does not teach or suggest this element. The importance of managing temperature and humidity in rebreathable systems is recognized. Expired air is humid and warm. Humid and warm air rapidly breaks down CO_2 absorption

material, leading to increased resistance to breathing and instrument degradation. The Michielsen apparatus attempts to reduce the destructive properties of humidity and heat by using two CO_2 chambers. With two chambers, one chamber acts as a sacrificial chamber in that it can breakdown or malfunction, without affecting the operation of the apparatus as a whole (see col. 6, lines 30-44). The present invention, in contrast, achieves long lifespan without a need for an additional sacrificial chamber.

Furthermore, Michielsen does not teach or suggest preventing moisture from communicating with the CO_2 absorption chamber as recited in claim 26. In fact, Michielsen explicitly teaches confining "the damaging effects of moisture accumulation" during initial use to a CO_2 absorption chamber **16** (see col. 6, lines 30-34), whereas the presently claimed invention recites preventing moisture from entering the CO_2 absorption chamber. Subsequently, Michielsen contemplates "trapping" moisture in compartment 13 to hopefully prevent moisture from reaching the second compartment 14 (col. 6, line 48). Applicant emphasizes, however, that the Michielsen trapping mechanism is not equivalent to removing moisture, as trapped moisture may still remain in the air stored in the breathing bag, which moisture is still capable of affecting the second absorber material as well, thereby shortening instrument lifespan. The presently claimed invention, accordingly, represents a significant improvement over Michielsen in that breakdown of the CO_2 absorbent material is substantially prevented. This results in a user not having to overcome the resistance to breathing encountered associated with the Michielsen apparatus when the first CO_2 absorbent breaks down and the trapped moisture then affects the second absorbent chamber. Therefore, the user can use the presently claimed invention for an extended period of time and is suitable for the hypoxic training purposes intended.

Because Michielsen does not teach or suggest each element of claim 1, such as a reservoir contained within a casing of selectively variable volume, or a demand valve in the inspiratory path to facilitate communication with ambient air,

Applicant requests the 102(b) rejection of claim 1, and claims dependent therefrom, be reconsidered and withdrawn.

Claim Rejections 35 U.S.C. 103 Rejection (Items 5-8)

Claims 3-5, 8, 11, 12-14, 18, 20, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michielsen in view of Lewis et al. (4,764,346). In view of the amendments and arguments presented herein, Applicant traverses this rejection.

The Office acknowledges that Michielsen does not expressly disclose a reservoir placed inside a chamber. Michielsen therefore, certainly does not disclose a reservoir contained in a casing of selectively variable volume as recited in amended claim 1. Lewis does not, either alone or in combination with Michielsen, teach a casing of selectively variable volume that contains a reservoir.

Rather, Lewis is directed to an apparatus for administering oxygen and anaesthesia, which delivers pressurized oxygen and an anaesthetic agent to a patient. The chamber or canister disclosed in Lewis is of a fixed volume and there is no teaching or suggestion in Michielsen or Lewis, either alone or in combination, to provide a user-selectable chamber volume to thereby control the reservoir volume. Because the pending rejected claims all depend from claim 1, Applicant requests the 103 rejection be reconsidered and withdrawn for the pending claims.

Furthermore, even if Lewis is combined with Michielsen, the combination of references does not teach or suggest the claimed invention. Lewis only teaches, at most, that the reservoir of Michielsen be placed within a chamber. As noted by the Office, this provides the functionality of protecting the relatively fragile reservoir. There is no teaching or suggestion in the combination of Lewis and

Michielsen, however, for user-manipulation of the chamber volume to provide hypoxic breathing, as provided by the presently claimed invention.

A more important reason for the Lewis canister, besides providing protection, is to allow for a means of regulating the pressure between the inside of the canister and the flexible reservoir bag in order to promote rebreathing via the bellows structure 13. The canister of the present invention, however, is one of variable volume, which volume can be permanently set at a particular volume and then readily changed at will. While the two canisters share the function of protecting the flexible reservoir bag, the primary purpose of the two is significantly different. As the Lewis canister does not provide for any means of varying its internal volume in order to directly limit the extent of inflation which the reservoir bag held within can enjoy, it is not able to achieve the beneficial functional outcomes that the present invention does.

Accordingly, both references lack the presently claimed element related to a flexible thermo-conductive reservoir bag which resides within a canister of variable volume (the volume of which is specifically selected by the user and will only change when the user physically alters the apparatus so as to enable a larger or a smaller volume to be achievable. If the apparatus is not so altered, the initial selected volume will remain the volume that is achievable by the apparatus, regardless of influences external to it as the reservoir bag itself cannot be physically interfered with without the apparatus first being disassembled).

Lewis is further cited for teaching the use of apertures (25a) for the purpose of "maintaining pressure" within the system. The Office alleges "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Michielsen to include the apertures (25a), as taught by Lewis for the purpose of maintaining pressure within the system." Applicant respectfully traverses this rejection.

First, the aperture in Lewis is located between an internal membrane that partially encloses the absorptive material and a second membrane, the flexible reservoir bag. This aperture is essential to the Lewis apparatus. It enables communication between the air immediately surrounding the absorptive chamber and the air within the reservoir bag and is designed to allow for the passage of gases into the reservoir bag.

The aperture in the present invention, however, enables communication between the air within the reservoir bag and the ambient air adjacent to the sidewall of the apparatus. The aperture in the present invention is not essential but rather is preferred, in a form that enables it to be selectively opened or to exist only in the form of a demand valve. It is not designed to "maintain pressure" but rather to selectively supplement the air with oxygen or to supplement the air available to be inspired when the available volume is insufficient. The purpose of the aperture in the present invention is not to maintain pressure.

The communication made possible by the aperture in Lewis concerns movement of air during an exhalation. The air moves through the aperture as it passes through the absorptive material as the user breathes out. The communication through the aperture in the present invention were it to be present, however, occurs during an inspiration such that the air only communicates with the ambient air as it is drawn upwards through the absorptive material as the user breathes in.

As such, even if Lewis is combined with Michielsen, there is no teaching or suggestion by the references, either alone or in combination, to an aperture that is in fluid communication with ambient air (as recited in claim 12). As discussed, such an aperture placement is specifically taught against by Michielsen, as Michielsen seeks to isolate the breather from the surrounding environment (e.g., water, smoke or other contaminated air), so that an aperture placement to ambient air would produce an inoperative combination. Because Michielsen

teaches away from having an aperture in communication with ambient air, as well as the combination of the Lewis and Michielsen references producing an inoperative combination, Applicant specifically requests the 103 rejection of claim 12 be reconsidered and withdrawn.

Claim 21 is rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Michielsen in view of Smith (6,536,430). Smith is cited for allegedly disclosing "the use of an oxygen analyzer (14) for the purpose of ensuring the patient is receiving sufficient oxygen and the rebreathing device is functioning properly." Similar to the deficiencies of Michielsen and Lewis, however, Smith (by itself or in combination with any of the other cited references) does not teach or suggest a reservoir "contained within a casing of selectively variable volume", or a demand valve in the inspiratory path to facilitate communication with the ambient air of claim 1. Because claim 21 is depends from claim 1, Applicant request the 103 rejection of claim 21 be reconsidered and withdrawn.

In view of the arguments and amendments made herein, Applicant requests the 103(a) rejections be reconsidered and withdrawn.

CONCLUSION

In view of the foregoing, this case is considered to be in condition for allowance and passage to issuance is respectfully requested.

It is believed that a fee for a one-month extension of time is due with this submission. Included herewith is a petition for extension of time and electronic payment is made via the EFS-web system. If this is incorrect, however, or there is a problem with the electronic payment, please credit or deduct the appropriate fee for this submission from Deposit Account No. 07-1969.

Respectfully submitted,

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